Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed August 3, 2009. Currently, claims 1, 27, 29-33, 40-49, 59, and 60 remain pending of which claims 29-33 were previously withdrawn. Claims 1, 27, 40-49, 59, and 60 have been rejected. Claim 40 has been amended to further clarify the relationships among the components. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 102

Claim 1 was rejected under 35 U.S.C. 102(b) as anticipated by Hannam et al. (U.S. Patent No. 5,649,959), hereinafter Hannam. After careful review, Applicant must respectfully traverse this rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, *814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).* "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990) *(See MPEP § 2131).* Nowhere does Hannam appear to teach or suggest, "a flexible plug having a center, a top surface, and a bottom surface, the plug being sized to circumferentially cover the blood vessel puncture site and further being sufficiently flexible to conform to and seal the blood vessel puncture site", as recited in claim 1.

Instead, Hannam appears to disclose the use of a long, narrow strip which serves as an intravascular anchor for a filament which an extravascular member engages to seal the incision from the flow of fluids therethrough. The Examiner has made reference to two passages in Hannam, namely column 7, lines 34-37 and column 7, lines 41-46, which appear to describe alternative constructions for the anchor member (30). In the paragraph including lines 34-37, the anchor member is characterized as "a relatively thin, narrow

strip of material" which is "sufficiently rigid such that once it is in position within the artery it is resistant to deformation to preclude it from bending and thus passing back through the puncture or incision through which it was first introduced." Accordingly, that embodiment appears to be both rigid and narrow precluding it from being flexible and/or wide enough to serve the required limitations.

The second passage, quoted in the current office action, appears to discuss an alternate embodiment which may: "expand or unfold to an enlarged configuration suitable for closing off the puncture 28 generally along the artery." Attention is drawn to the fact that the first paragraph does not appear to make reference to covering or sealing the puncture or incision and the second paragraph does not appear to disclose that the anchor member is capable of sealing the incision, but only describes closing off the incision along the artery to preclude it from passing back through the puncture or incision without any disclosure in the intervening text that teaches or even suggests that the configuration is anything other than "a relatively thin, narrow strip of material" of the earlier paragraph or that the anchor has a width capable of closing off the incision laterally. The disclosure of Hannam is characterized as follows in the Summary of the Invention:

> "The closure assembly of the present invention preferably generally includes an anchor member, a gelatinous or similar material which forms a sealing means, and a filament member. The anchor member includes a tissue engaging portion and is configured to pass through the opening in one direction, but is resistant to passage therethrough in the opposite direction. The sealing means includes a gelatinous material, such as a tissue glue, including a cyanoacrylate, or fibrin material which engages the filament member as the gelatinous material dries or cures. The filament member is an elongate member that is preferably formed of a suture material having a length which is sufficient to be connected between the anchor member and the sealing means while extending across the wall of the vessel, duct or lumen."

Although the anchor may temporarily and partially cover the opening in the vessel wall, it appears that the only sealing means is supplied outside of the vessel. The function of the anchor appears to be only that of anchoring the filament such that the sealing means may engage the filament without the sealing means and the filament being ejected from the incision. As noted earlier, Hannam explicitly notes that: "Additionally,

the clot formed by the gelatinous material 52 will absorb any bleeding from the tissue surrounding the incision 28 and will also absorb any blood which may seep past the anchor member 30." indicating that Hannam acknowledges that his anchor does not provide an effective seal. (Col. 12, lines 35-39) Further, Figs. 1-5 appear to indicate that the puncture or incision through which the anchor is inserted has a dimension, presumably a diameter, which is about 2.5-2.7 times at least one dimension of the anchor in its expanded state within the vessel.

Although the flexible plug of the currently pending claims may be used with a hemostatic material if desired, claims 1 and 40 both recite that the plug is capable of circumferentially covering the blood vessel puncture site and sealing the puncture site. Sealing the puncture is a function provided by the flexible plug and does not rely upon a hemostatic body to provide a sealing means as apparently required in the disclosure of Hannam. The hemostatic material of claim 1 is recited as a component of a release mechanism coupled to the flexible plug rather than as the sealing element of the claim. Since Hannam does not appear to disclose an anchor capable of covering the puncture site and also capable of sealing the puncture in the absence of, or prior to the addition of, additional structure, Hannam fails to disclose *each and every element as set forth in the claim* and to disclose the elements in as complete detail as is contained in the claim. Applicants respectfully request that the rejection of claim 1 be withdrawn.

It is noted that the Examiner's assertion that a suture (36) would inherently be secured to the hemostatic body since the body is an adhesive is not necessarily correct as required to establish inherency. Anti-stick/release materials are well known in the adhesive art. Further, adhesive materials are often non-adhesive upon curing. The cited passage of Hannam appears to preferably cure the gelatinous material to adhere to the filament rather than to necessarily do so. If the gelatinous material does cure to adhere to the filament, it is said to do upon reacting "with the body fluids of the patient" apparently indicating that the fluids in question have escaped from the vessel through the puncture thereby strongly suggesting that the puncture has not been sealed by the anchor as asserted by the Examiner.

Claim Rejections – 35 USC § 102/103

The rejection of claim 27 as anticipated by Hannam under 102(b) or, in the alternative, under 103(a) as obvious over Hannam in view of Haaga (U.S. Patent No. 5,254,105) appears to be a rejection under MPEP 2112, III. which requires that the missing feature of the claim be inherently present. Initially, it should be noted that claim 27 depends from claim 1 and adds significant limitations thereto, claim 1 having been shown to be not anticipated by Hannam. The disclosure of Haaga does not appear to overcome the identified deficiencies of the Hannam reference as applied to independent claim 1. For at least this reason, claim 27 appears to be patentable over either Hannam or Hannam in view of Haaga. In addition, the surface of the injectable material of Hannam does not appear to be inherently differentiated from the bulk material and thus does not appear to "encapsulate" the remaining material. As described at column 6, lines 39-41, the "gelatinous" material of Hannam is a viscous material which appears to be sufficiently flowable to allow it to be injected into the wound. Were it to be contained, it would appear to become unsuited for the mode of delivery contemplated by Hannam. Further still, the claim in question recites that the hemostatic material is encapsulated rather than that it becomes encapsulated as might be the case if the injected material of Hannam forms a skin upon reacting with the bodily fluids of the patient. The terms "encapsulation" or "encapsulated" do not appear to be present in the disclosure of Hannam as applied to the gelatinous material, but appears only in the context of subsequent encapsulation of the anchor by tissue within the vessel.

It would appear that the only applications of a gelatin surface contemplated in the cited passage of Haaga would be "medication capsules" and "a coating for a fabric" graft, neither of which would appear to teach encapsulation of a hemostatic fluid for injection into a wound, said fluid being capable of reacting with fluids with which it comes into contact. For at least these reasons, it does not appear that either Hannam or Hannam in view of Haaga anticipates or renders obvious the subject matter of claim 27 and Applicants respectfully request that the rejection be withdrawn.

Claim Rejections – 35 USC § 103

Claims 40-49 and 59-60 were rejected under 35 U.S.C. 103(a) as being

unpatentable over Hannam in view of Kensey et al. (U.S. Patent No. 4,890,612). After careful review, Applicant must respectfully traverse this rejection.

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03).

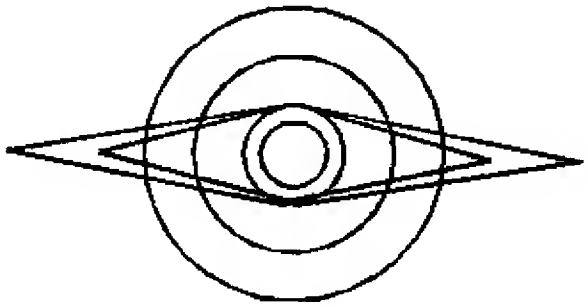
As an initial matter regarding claim 40, it is unclear whether the element **38** to which the Examiner refers is plunger member (38) of Hannam or pusher means (38) of Kensey. In either case, it is unclear how a pusher or plunger might couple a "flexible plug" to a "hemostatic body" particularly since neither term seems to appear in either Hannam or Kensey. The Examiner is invited to clarify his intent in a future non-final Office Action.

Further, it is unclear that either "a relatively thin, narrow strip of material" of Hannam or toggle (106) of Kensey is sufficiently wide to "circumferentially cover the blood vessel puncture site" as recited in pending claim 40. Hannam has been discussed above.

The dimension provided for the outside diameter elongate tube (32), 8 French = 2.667 mm appears to be incompatible with the later cited dimensions provided for the closure member (30) of Figs. 3 and 4 cited by the Examiner which is said to have an anchor diameter of 2-3 mm and a thickness of 1-2 mm at col. 5, lines 22-26 suggesting that the closure member of the figures could not be folded to an outside dimension of less than 4 mm. The elongate tube of 8 French must be used with the narrow toggle of Figs. 6 and 7 which appears to be similar to the toggle of Hannam.

In determining whether the closure (30), as disclosed by Kensey, is capable of circumferentially covering the puncture, one must turn to the cited Figs. 3 and 4. As depicted, the outer diameter of the tube (32) appears to determine a minimum dimension for the puncture which has additionally accommodated the larger introducer sheath (26). The tube used to deliver the embodiment of those figures, has been measured to be approximately 3.75 times the diameter of the anchor portion of closure member (30) or about 7.5 mm to about 11.25 mm. These dimensions lead to a circumferential puncture length of about 23.6 mm to about 35.3 mm. If the waist of the puncture closes about the

anchor as illustrated, then simple trigonometry allows one to calculate that the partially collapsed puncture will have a length of between about 11.4 mm to about 17.3 mm which is greater than the stated diameter of the disk of Figs. 3 and 4 and thus not capable of circumferentially covering the puncture. See the sketch below which illustrates the calculated range of dimensions of the puncture in comparison to the stated ranges of dimensions of the closure. If the puncture has a dimension which accommodates the introducer sheath; if the smaller anchor dimension is used in the calculation; or even if the puncture is allowed to close to a greater degree, the portion of the puncture not circumferentially covered by the closure would be even greater than illustrated. If the opening in the vessel closes about the anchor to a greater degree, the longitudinal extent of the opening would be even greater. Accordingly, the dimensions provided in the disclosure of Kensey do not appear to lead to an anchoring disk which is capable of covering, much less sealing, the opening of the vessel even in the most favorable combinations of those dimensions as will be seen by comparing the smaller diamond to the largest disk .



Accordingly, the disclosure of Kensey appears to be limited to closures, whether narrow or circular, which do not circumferentially cover the punctures through which they are delivered. Further the disclosure of Kensey appears to be limited to closures which rely upon one of two operating principles. In the embodiments of Figs. 3 and 4, Kensey appears to rely upon a small disk providing incomplete closure which is "held taut and secured in position on the patient's skin". In the embodiment of Figs. 6 and 7 Kensey, like Hannam, appears to rely upon a narrow toggle to anchor a filament which serves to position sealing element (106) within the wound tract and protruding somewhat

into the vessel as depicted in Figs. 9 and 10 rather than relying upon toggle (106) to contact and seal the puncture. In either case, the disclosure of Kensey does not appear to include a disk to intravascularly seal a blood vessel puncture site, said disk being sized circumferentially to cover the blood vessel puncture site, and a hemostatic body to seal the blood vessel puncture. Modification of either the embodiment of Figs. 3 and 4 or the embodiment of Figs 6-10 to include both a circumferentially sealing disk and a hemostatic body would appear to impermissibly alter the respective principles of operation of Kensey. (MPEP 2143.01, VI.) Further, the combination of Hannam with Kensey appears to be merely repetitive of the use of a narrow toggle with a hemostatic sealing body and does not address the absence of the disk found in claim 40 which recites that the disk intravascularly seals the vessel by covering it circumferentially and anchors a hemostatic body within the puncture site. Although the Examiner has argued, regarding dependent claims 44-49 and 59-60, that changing the shape of the toggle of Hannam to the disk of Kensey is an obvious modification, the shape change is insufficient to ensure that the a disk-shaped anchor is capable of circumferentially covering the puncture and as demonstrated above the disk of Kensey does not appear to do so. For at least the above reasons Hannam in view of Kensey does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness and Applicants respectfully request that the rejection of independent claim 40 be withdrawn.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

Accordingly, claims 41-49 and 59-60, which depend from nonobvious independent claim40, also are believed to be nonobvious and Applicants respectfully request that the rejections be withdrawn.

In the Response to Arguments, the Examiner has focused on a single aspect of the argument with respect to whether Hannam discloses a "release mechanism" as that term is used in the pending application. Granting solely for the sake of argument that

"severing the filament proximal of the gelatinous material" may be construed as "releasing" the proximal end of the filament from the more distal end of the filament, Applicants note that the release mechanism of the claim has additional structure and characteristics which must also be met for anticipation: "a release mechanism including a hemostatic material coupled to the center of the flexible plug and a resilient extension member coupled to the hemostatic material opposite the flexible plug, the release mechanism positioning and releasing the flexible plug intravascularly at the blood vessel puncture site". Initially, it will be noted that the flexible plug of the claim does not appear to be present in Hannam. The release mechanism also requires "a resilient extension member coupled to the hemostatic material opposite the flexible plug. The filament (36) of Hannam does not appear to be releasably coupled to the proximal end of the hemostatic material of Hannam and the cutting of the filament of Hannam above the skin appears to take place well away from the gelatinous material and indeed well above the skin as illustrated in Figs. 9 and 21. Further, the filament does not appear to be "resilient" as recited in claim 1. The Examiner has proposed that enlarged head member (68), a component of the anchor plug (30) which is located distal of the gelatinous plug in Figs. 11-15, provides "a resilient extension member"; however that component of Hannam does not appear to be characterized as "resilient" and does not appear to be "coupled to the hemostatic material opposite the flexible plug" as recited in the claim. Further, the Examiner asserts that the suture and extension member combine to "position and release the plug". In those embodiments which include the identified extension member (68), Hannam discloses that it is "The syringe assembly 70 of this embodiment [which] functions as a positioning member" and further that it is the tissue which positions the gelatinous material and retains the anchor member. (Col. 15, lines 34-39)

As discussed in detail above, the narrow strip of Hannam does not appear to be sized to cover the puncture circumferentially and does not appear to seal the puncture since Hannam explicitly notes that: "Additionally, the clot formed by the gelatinous material 52 will absorb any bleeding from the tissue surrounding the incision 28 and will also absorb any blood which may seep past the anchor member 30." indicating that Hannam is aware that his anchor does not provide an effective seal. (Col. 12, lines 35-39) In discussing the toggle of Hannam, the Examiner quotes a passage from Hannam which

is said to indicate that the toggle is flexible which presumable has been taken to indicate that it is sufficiently flexible to form a seal. Instead, the toggle described in that passage appears to be flexible only for a short distance along a generally linear section of the artery and a "rigid" narrow strip such as the toggle of Hannam described at col. 7, lines 25-37 would appear to suffice for the purpose.

With respect to plunger (38) of Hannam "coupling" a hemostatic body to the flexible disk, the passage cited by the Examiner merely states that the plunger ejects the gelatinous material into the puncture such that the gelatinous material is adjacent to the anchor member. Here "couple" has been used in its ordinary dictionary meaning of "to fasten together" and there appears to be no indication in the cited text that the gelatinous material and the disk even come in contact (adjacency does not require contact), much less that they are fastened together. Surely the Examiner is aware that the statement that "the hemostatic body and the flexible plug would not be coupled without the plunger" is insufficient to support an assertion that the plunger, itself, serves to fasten the hemostatic body to the flexible plug as is required by the plain language of the claim.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reconsideration and withdrawal of the rejections is respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Date: Sept. 16, 2009

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